Food and Drug Administration Office of Regulatory Affairs

Summary Report

For Sample Number: 693966 13206137

TD Sample Number: **Import Sample Number**

This is an accurate reproduction of the original electronic record as of 12/10/2012

Sample Class: Normal Everyday Sample
Sample Flag:
Home District:

Sample Origin: Domestic
Sample Type: Official
Orig C/R and Records To: NWE-DO

Sample Basis: Other-Survl
Collecting District: NWE-DO
Collection PACs: 56D015

Product Name: Methylprednisolone Acetate (Glucocorticoid); Human - Rx/Single Ingredient; Small Volume Parenteral <

Product Description: Product is a liquid sterile compounded suspension filled in 5mL amber glass vials and labeled as

Collection Reason: Sample collected to assess the presence of unknown particulate matter in sterile drug product, lot #08102012@51, intended for intrathecal administration. Sample collected during an inspection and will be tested for sterility and undergo visual inspection.

Lab: NRL **Split Num:** 0 **Date Received:** 10/03/2012 **Date Out of Lab:** 12/10/2012

District Conclusion:
District Conclusion Made By:
District

Disposition Reason:
Disposition Authorized By:
Disposition Authorized Date:

Performing Org	PAC	LID	PAF	Compliance No	Lab Class-Description	Laboratory Status
NRL-MSB-K	56D015		NAR	70723-0	3 - Adverse Findings	Completed

12/12/12

Lab Conclusion

Viable microorganisms detected in twenty five (25) of twenty five (25) subs tested.
Yeast-like organisms detected in twenty five (25) of twenty five (25) subs tested.
Mold-like organisms detected in subs # 3, 4, 6, 7, 8, 9, 10, 11, 14, 16, 17, 18, 19, 20, 21, 22, 24 and 25.
No viable microorganisms detected from swabs taken from the exterior portion of the rubber stopper of each of twenty five (25) subs cultured in Sab-Dextrose (Sab-Dex) medium.
No obvious foreign material observed under direct visual examination of twenty five (25) of twenty five (25) subs individually examined.
All media, equipment, environmental and system controls were negative for growth.

Lab Conclusion Date	Lab Conclusion Made By
12/10/2012	Braut Taormina,Jasna

2012 DEC 14 AM 10 09
NWE DISTRICT OFFICE

Date: 12/10/2012 **Page:** 1 of 1

Flag:

ANALYST WORKSHEET	**1. PRODUCT** Methylpred. AC(PF) 80MG/ML Injectable	**2. SAMPLE NO.** 693966

3. SEALS X INTACT ___ NONE ___ BROKEN	**4. DATE RECEIVED** 10/3/2012	**5. RECEIVED FROM** William Baroletti	**6. DISTRICT OR LABORATORY** **NRL**

7. DESCRIPTION OF SAMPLE One brown paper bag officially sealed as "693966, 10/2/2012, Stacey S. Degarmo, Investigator" containing a total of fifty (50) intact units of product. Form FDA 525 attached. Sample received at ambient temperature.

8. NET CONTENTS	_NOT APPLICABLE DECLARE/UNITS 5 ml _X_NOT DETERMINED AMOUNT FOUND ___ ___UNITS EXAMINED % OF DECLARED ___	**9. LABELING**	________ORIGINAL SUBMITTED 1 SET PHOTOCOPIES SUBMITTED 2 SETS COPIES OF PHOTOCOPIES SUBMITTED

10. SUMMARY OF ANALYSIS

A. CONTAINER: Round 10ml capacity amber glass vial with a grey rubber stopper under a crimp metal closure and a white pop off plastic dust cover measuring approximately 4.5 cm in height and 2.0 cm in base diameter,

B. LABELING: Commercially manufactured pressure sensitive paper label affixed around glass vial.

C. CODE: "Lot#08102012@51 Discard after 2/6/2013" printed on paper label affixed around glass vial.

D. PRODUCT: White opaque free flowing suspension.

E. ANALYSIS: Examination for viable microorganism. Sterility analysis. Direct visual examination.
Exterior rubber stopper for objectionable microorganisms.

F. METHOD: USP 35-NF 30, 2012 Section <71> Sterility Test.Vol.1 pp 69-74
Sterility Analytical Manual, 3rd Edition, August 1997, pp. 5-17
See p. 3 for methodology.

G. UNITS TESTED: Twenty five (25) units tested.

H. RESULTS: Viable microorganisms detected in twenty five (25) of twenty five (25) subs tested
Yeast-like organisms detected in 25 of 25 subs tested.
Mold-like organisms detected in subs #3, Sub# 4, Sub# 6, Sub# 7, Sub# 8, Sub# 9, Sub# 10,Sub# 11, Sub#14, Sub#16, Sub#17 Sub#18, Sub#19, sub# 20, Sub# 21, Sub# 22, sub#24 and sub#25.
No viable microorganisms detected from swabs taken from the exterior portion of the rubber stopper of each of 25 subs cultured in Sab-Dextrose (Sab-Dex) medium.
No obvious foreign material observed under direct visual examination of twenty five (25) of twenty five (25) subs individually examined.
All media, equipment, environmental and system controls were negative for growth .

11. RESERVE SAMPLE: Brown paper bag officially sealed "693966, 10/3/2012, Haydee B. Romero" containing a total of twenty five (25) intact units and twenty five (25) empty units of product. Each unit is identified as "693966, 10/3/2012, HR". Two (2) whirl pak bags officially sealed "693966, 10/10/12, Haydee B. Romero, Analyst". Each bag contains four isolates on Sab-Dextrose slant; slants identified as "Sample # 693966 Sub#1 (pink colony)10/10/12 HR", Sub #3-1 (pink colony), Sub # 3-2 (gray colony) and sub # 9 (pink colony), respectively. One bag was shipped to CDC on 10/11/12, for further identification and the other bag held within a secured refrigerator at NRL. Sample kept under lock and key until returned to sample custodian

12. ANALYST SIGNATURE **Haydee B. Romero** (x) Broke Seal 10/3/12 Haydee B Romero	**13. WORK SHEET CHECK**	a. BY Ph.D. b. DATE 12/10/12
(Daniel J. O'Reilly) JASNA BRAUN-TAORMINA	**14. DATE REPORTED**	12/10/12

NRL-MSB.1.60Version1.0
Electronic Version of 431

Attachments: A - C

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GENERAL CONTINUATION SHEET	PRODUCT Methylpred AC (PF) 80MG/ML Injectable	SAMPLE NO. 693966

STERILITY MEDIA & EQUIPMENT CONTROL SHEET

Incubation Started: 10/4/12 **By:** VN

CONTROLS:

Environmental Monitoring: Two Blood agar plates exposed for the duration of the analysis. (Maximum time of exposure is 1 hour)

Agar Plate Growth: 0 bacterial colonies

0 mold colonies

0 yeast colonies

Media and Equipment Quality Assurance Numbers and Control Results:

ITEM	QA #	Results	ITEM	QA #	Results
Thioglycollate Broth	276-12	Neg	Millipore Forceps	N/A	N/A
Soybean Casein Digest Medium	177-12	Neg	Manifolds	N/A	N/A
Rinse Fluid A	N/A	N/A	Syringes R'd 3/22/05 BD 10CC 21G, 1 1/2"	Lot 4275726A	Neg
Rinse Fluid D	N/A	N/A	Beakers	131-12	N/A
Malt Extract Agar(MEA)	276-12	Neg	Chlortetracycline	242-12	N/A
3% Hydrogen Peroxide R'd 3/27/12	Lot11524	N/A	Swabs R'd 9/14/11 Exp 2016/05	Lot2828	Neg
70%Filter Sterilized alcohol	264-11	N/A	Membranes .22microns	N/A	N/A
			Membranes .45microns	N/A	N/A
Wipes	176-12	N/A	10" Forceps	047-12	Neg
10 ml Sabdex Broth	276-12	Neg	Phosphate Buffer	276-12	Neg
System Control	011-11	Neg	Other/Blood Agar BBL R'd 9/25/12	Lot 2220296	Neg

Exp 2012.11.30

22.5+/-2.5C Incubator 1776

32.5+/-2.5 Incubator 1958

Neg =Negative

N/A=Not Applicable

ANALYST(S): Hayden B Romero

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General continuation sheet	**Product** Methylpred. AC(PF)80 MG/ML Injectable	**Sample No.** 693966

Methodology-Direct inoculation
Sample preparation , swabbing under dust cap and sterility testing (Vials)

1. Sample Preparation:
The number of unit (s) (Twenty five (25) to be examined was/[✓ were] removed from the sample container under the laminar flow hood and all units were placed in sterile bag. The bag was disinfected using *3% H2O2* disinfectant solution. The disinfected bag then placed inside the disinfected stainless steel pass thru of the clean room and left for an hour. Analyst wore sterile latex rubber gloves, sterile sleeve, hair net and a mask during this procedure ( ).

2. Preparation of the analytical area and personnel:
Within the gowning area the analyst (s) dressed in a garment (s) consisting of hair net, mask, shoe cover, sterile hood, sterile jumpsuit, sterile booties and sterile latex rubber gloves. All transfers of product to growth medium were aseptically performed within a horizontal laminar flow hood (LFH) and the Bio safety cabinet (BSC) located within the bio-clean room. All surfaces within the LFH and BSC were thoroughly disinfected with *Filter sterilized 70% alcohol* prior to analysis of the sample ( ).

3. Analytical procedures:
All units were placed within the LFH. For each unit the flip off dust cap was aseptically removed and by using sterile cotton swap moisten in sterile *PB Buffer*, the exposed rubber stopper area was wiped and the swab was aseptically transferred to a tube containing 10 ml of sterile *Sab-Dextrose* (Sab-Dex) medium ( ). All tested unit (s) was/were then transferred to another LFH hood within the clean room for disinfection ( ). Each unit was wiped with *3% H2O2* disinfectant solution and left to dry for up to one (1) hour ( ). All disinfected unit(s) was/[✓ were] transferred to the BSC within the clean room ( ). Within the BSC within the Bio clean room. These units were again disinfected with *Filter sterilized 70% alcohol* and left to air dry under the BSC ( ). For each unit using sterile 10 CC syringe 2.5 ml of the contents were aseptically delivered into SCD medium and 2.5 ml delivered into Fl. Thio. medium ( ).
The remaining droplets in the syringe were then aseptically transferred unto a MEA agar plate ( ).

4. Controls:
Media: All tubes of Fl. Thio medium, SCD medium , 10 ml SAB-DEX medium ,blood agar plates, and *MEA* agar plates were pre-incubated prior to use. One un-inoculated tube of each medium was incubated with the test tubes as closed controls ( ).
Swab: One sterile swab was aseptically transferred to a tube containing 10 ml of sterile Sab-DEX medium
Equipment: Two (2) 10" forceps were each dipped into one tube each of SCD and Fl. Thio. media ( ).
Syringe: Two (2) syringes were used to withdraw media from each of SCD and Fl. Thio. Media and expelled it back to their respective tubes.
System control: To monitor the sterility of the analytical technique, a system control was used. *One sterile vial of 0.1% peptone water was aseptically opened to expose the rubber stopper by using a sterile 10" forceps, this unit was tested using the same analytical procedure employed in setting up the sample* ( ).

5. Environmental: Two *blood* agar plates were exposed for the duration of the analysis on the right and left sides of the hood working area for each step of the analysis( ). One tube each of Fl. Thio. medium, SCD medium and SabDex medium were opened and exposed for the duration of the analysis as opened controls ( ).

6. Incubation:
Tubes of SCD medium were incubated 14 days at 22.5 +/- 2.5 °C. Tubes of Fl. Thio. medium were incubated 14 days at 32.5+/ - 2.5 °C. Tubes of Sab-Dextrose medium were incubated 14 days at 30 °C. All tubes were observed periodically for indication of possible growth (i .e. turbidity) ( ). The MEA agar plates were incubated at 22.5 +/ - 2.5 °C and were observed for growth for up to 14 days ( ).

7. **Subculture of presumptive positive tubes:** See pg 10-13

( )= Analyst performing procedure

ANALYST(S) Hayder B Romero	PAGE 3 OF 13 PAGES

GENERAL CONTINUATION SHEET	PRODUCT Methylpred. AC (PF) 80MG/ML Injectable	SAMPLE NO. 693966

DAILY OBSERVATIONS

SAMPLE TEST

Date Incubation Started 10/4/12 HR

[✓ SUB] / Composite	Thio/SCD DAYS INCUBATED														Final Results
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	
1	(+)/(+)				(+)/(+)	(+)/(+)	(+)/(+)	(+)/(+)			(+)/(+)	(+)/(+)	(+)/(+)	(+)/(+)	See page 1 and pages 10-13 ↓
2	(+)/(+)				(+)/(+)	(+)/(+)	(+)/(+)	(+)/(+)			(+)/(+)	(+)/(+)	(+)/(+)	(+)/(+)	
3	(+)/(+)				(+)/(+)	(+)/(+)	(+)/(+)	(+)/(+)			(+)/(+)	(+)/(+)	(+)/(+)	(+)/(+)	
4	(+)/(+)				(+)/(+)	(+)/(+)	+/(+)	+/(+)			+/(+)	+/(+)	+/(+)	+/(+)	
5	(+)/(+)				(+)/(+)	(+)/(+)	(+)/(+)	(+)/(+)			(+)/(+)	(+)/(+)	(+)/(+)	(+)/(+)	
6	(+)/(+)				(+)/(+)	(+)/(+)	+/(+)	+/(+)			+/(+)	+/(+)	+/(+)	+/(+)	
7	(+)/(+)				(+)/(+)	(+)/(+)	(+)/(+)	(+)/(+)			(+)/(+)	(+)/(+)	(+)/(+)	(+)/(+)	
8	(+)/(+)				(+)/(+)	(+)/(+)	(+)/(+)	(+)/(+)			(+)/(+)	(+)/(+)	(+)/(+)	(+)/(+)	
9	(+)/(+)				(+)/(+)	(+)/(+)	+/(+)	+/(+)			+/(+)	+/(+)	+/(+)	+/(+)	
10	(+)/(+)				(+)/(+)	(+)/(+)	+/(+)	+/(+)			+/(+)	+/(+)	+/(+)	+/(+)	
11	(+)/(+)				(+)/(+)	(+)/(+)	+/+	+/+			+/+	+/+	+/+	+/+	
12	(+)/(+)				(+)/(+)	(+)/(+)	(+)/(+)	(+)/(+)			(+)/(+)	(+)/(+)	(+)/(+)	(+)/(+)	
13	(+)/(+)				(+)/(+)	(+)/(+)	(+)/(+)	(+)/(+)			(+)/(+)	(+)/(+)	(+)/(+)	(+)/(+)	
14	(+)/(+)				(+)/(+)	(+)/(+)	+/+	+/+			+/+	+/+	+/+	+/+	
15	(+)/(+)				(+)/(+)	(+)/(+)	(+)/(+)	(+)/(+)			(+)/(+)	(+)/(+)	(+)/(+)	(+)/(+)	
DATE / INITIAL	10/5 HR	10/6 W	10/7 W	10/8 H	10/9 HR	10/10 HR	10/11 HR	10/12 HR	10/13 W	10/14 W	10/15 HR	10/16 HR	10/17 HR	10/18 HR	

Upon receiving The sample a direct visual examination was done. No obvious foreign material observed under direct visual examination of The Twenty five (25) subs individually examined.

+ = Obvious growth observed.

(+) = Presumptive positive, unable to identify growth due to the turbidity nature of the product, all Thio/SCD tubes were streaked to MacConkey agar, Soybean Casein Digest agar, And Malt extract agar after 14 Day incubation.

W = Weekend H = Holidays

ANALYST(S) Haydee B Romero

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GENERAL CONTINUATION SHEET	PRODUCT Methyl pred. AC (PF) 80MG/ML Injectable	SAMPLE NO. 693966

DAILY OBSERVATIONS

SAMPLE TEST

Date Incubation Started 10/4/12 HR

SUB / Composite	Thio/SCD						DAYS INCUBATED								Final Results
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	
16	(+) (+)				(+) (+)	(+) (+)	(+) (+)	(+) (+)			+ (+)	+ (+)	+ (+)	+ (+)	See page #1 and page 10-13
17	(+) (+)				(+) (+)	(+) (+)	(+) (+)	(+) (+)			+ (+)	+ (+)	+ (+)	+ (+)	
18	(+) (+)				(+) (+)	(+) (+)	(+) (+)	(+) (+)			+ (+)	+ (+)	+ (+)	+ (+)	
19	(+) (+)				(+) (+)	(+) (+)	(+) (+)	(+) (+)			+ (+)	+ (+)	+ (+)	+ (+)	
20	(+) (+)				(+) (+)	(+) (+)	(+) (+)	(+) (+)			(+) (+)	(+) (+)	(+) (+)	(+) (+)	
21	(+) (+)				(+) (+)	(+) (+)	(+) (+)	(+) (+)			(+) +	(+) +	(+) +	(+) +	
22	(+) (+)				(+) (+)	(+) (+)	+ (+)	+ (+)			+ (+)	+ (+)	+ (+)	+ (+)	
23	(+) (+)				(+) (+)	(+) (+)	(+) (+)	(+) (+)			(+) (+)	(+) (+)	(+) (+)	(+) (+)	
24	(+) (+)				(+) (+)	(+) (+)	+ (+)	+ (+)			+ (+)	+ (+)	+ (+)	+ (+)	
25	(+) (+)				(+) (+)	(+) (+)	(+) (+)	(+) (+)			(+) (+)	(+) (+)	(+) (+)	(+) (+)	
System Control	- -				- -	- -	- -	- -			- -	- -	- -	- -	No Growth
Open Media	- -				- -	- -	- -	- -			- -	- -	- -	- -	
Closed Media	- -				- -	- -	- -	- -			- -	- -	- -	- -	
Syringes	- -				- -	- -	- -	- -			- -	- -	- -	- -	
10" Forceps	- -				- -	- -	- -	- -			- -	- -	- -	- -	
DATE / INITIAL	10/5	10/6 W	10/7 W	10/8 H	10/9	10/10	10/11	10/12	10/13 W	10/14 W	10/15	10/16	10/17	10/18	

See page 4 for Direct visual examination

- = No Growth
+ = obvious growth observed
(+) = Presumptive positive, unable to identify growth due to the turbidity nature of the product. All Thio/SCD Tubes were streaked TO MacConkey agar, Soybean Casein Digest agar and Malt Extract agar after 14 day incubation.
W = weekend H = Holiday

ANALYST(S) Haydee B Romero

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GENERAL CONTINUATION SHEET	PRODUCT Methylpred. AC(PF) 80MG/ML Injectable	SAMPLE NO. 693966

DAILY OBSERVATIONS

From swabs Taken from The exterior portion of the rubber stopper of each sub.

SAMPLE TEST

Date Incubation Started 10/4/12 br

SUB / Composite	swab in Sab Dex broth							DAYS INCUBATED							Final Results
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	See pg 1
1	–				–	–	–	–			–	–	–	–	No Growth
2	–				–	–	–	–			–	–	–	–	
3	–				–	–	–	–			–	–	–	–	
4	–				–	–	–	–			–	–	–	–	
5	–				–	–	–	–			–	–	–	–	
6	–				–	–	–	–			–	–	–	–	
7	–				–	–	–	–			–	–	–	–	
8	–				–	–	–	–			–	–	–	–	
9	–				–	–	–	–			–	–	–	–	
10	–				–	–	–	–			–	–	–	–	
11	–				–	–	–	–			–	–	–	–	
12	–				–	–	–	–			–	–	–	–	
13	–				–	–	–	–			–	–	–	–	
14	–				–	–	–	–			–	–	–	–	
15	–				–	–	–	–			–	–	–	–	
DATE / INITIAL	10/5 br	10/6 W	10/7 W	10/8 H	10/9 br	10/10 br	10/11 br	10/12 br	10/13 W	10/14 W	10/15 br	10/16 br	10/17 br	10/18 br	

– = NO GROWTH

W= weekend L= Leave H= Holidays O= other (Explain)

ANALYST(S) Haydee B Romero

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NRL-MSB.NECC

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GENERAL CONTINUATION SHEET	PRODUCT Methyl pred. AC (PF) 80MG/ML Injectable	SAMPLE NO. 693966

DAILY OBSERVATIONS

From swabs taken from the exterior portion of the rubber Stopper of each sub.

SAMPLE TEST

Date Incubation Started 10/4/12 HR

[✓ SUB] / Composite	swab in Sab Dex broth 1	2	3	4	DAYS INCUBATED 5	6	7	8	9	10	11	12	13	14	Final Results see pg 1
16	–				–	–	–	–			–	–	–	–	No Growth
17	–				–	–	–	–			–	–	–	–	
18	–				–	–	–	–			–	–	–	–	
19	–				–	–	–	–			–	–	–	–	
20	–				–	–	–	–			–	–	–	–	
21	–				–	–	–	–			–	–	–	–	
22	–				–	–	–	–			–	–	–	–	
23	–				–	–	–	–			–	–	–	–	
24	–				–	–	–	–			–	–	–	–	
25	–				–	–	–	–			–	–	–	–	
Blank control	–				–	–	–	–			–	–	–	–	
N/A															
DATE / INITIAL	10/5 HR	10/6 W	10/7 W	10/8 H	10/9 HR	10/10 HR	10/11 HR	10/12 HR	10/13 W	10/14 W	10/15 HR	10/16 HR	10/17 HR	10/18 HR	

W= weekend L= Leave H= Holidays O= other (Explain)

ANALYST(S) Haydee B Romero	Page 7 of 13 Pages

NRL-MSB.NECC

Electronic Version of 431A

GENERAL CONTINUATION SHEET	PRODUCT Methylpred. AC(PF) 80MG/ML	SAMPLE NO. 693966

Direct inoculation of product on agar media

N/A=Not Applicable

SUB # 10/4/12 HR	Agar type used	Plates read	Gram stain 10/9/12 HR	Subculture on 10/10/12 HR	Biochemical identification N/A	Results
1	MEA	+	Y	* Sab-dex Slant		Yeast-like organisms
2	↓	+	* *			↓
3		+	Y + M	* Sab-dex Slant		Yeast-like and Mold-like organisms.
4		+	* *			Yeast like organisms
5		+	↓			↓
6		+				
7		+				
8		+				
9		+	Y	* Sab-dex Slant		
10		+	* *			
11		+	* *			
12		+	↓			
13		+				
14		+				
15		+				
16		+				
17		+				
18		+				
19		+				
20		+				

ANALYST(S) Haydee B Romero

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Key: Y = Yeast-like cells M = Septated Hyphae

GENERAL CONTINUATION SHEET	PRODUCT MeThylpred. AC (PF) 80MG/ML Injectable	SAMPLE NO. 693966

Direct inoculation of product on agar media

N/A=Not Applicable

SUB # 10/4/12 HR	Agar type used	Plates read 10/18/12 HR 10/9/12 HR	Gram stain 10/9/12 HR	Subculture on N/A	Biochemical identification N/A	Results
21	MEA	+	* *			Yeast like organisms
22		+				
23		+				
24		+				
25		+				
Blank Control		NG	N/A			No Growth
N/A						

* A representative portion of positive subs were subcultured to SubDex slants in duplicate sets (Sub 1 = Yeast-like colony, sub 3 = Yeast like colony, mold-like colony and Sub 9 = yeast like colony), one set for shipment to CDC for further identification and the other set for storage at NRL.

** Colony morphology same as sub#1 and sub#9

Sab-Dex Agar Slant QA# 279-12

Microscope 282

ANALYST(S) Hayden B Romero

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GENERAL CONTINUATION SHEET	PRODUCT Methylpred. AC (PF) 80MG/ML Injectable	SAMPLE NO. 693966

Results from Subculture of THIO Medium on agar plates

N/A=Not Applicable

SUB #	Agar used 10/22/12 HR & 11/1/12 HR			Microscopic examination from 10/22/12 HR			Colony Morphology	Subculture on	Biochemical identification
10/18/12 HR	MAC	HEA	MSCD	MAC	HEA	MSCD	10/22/12 HR	N/A	N/A
1	NG	NG	NG	N/A	N/A	N/A	N/A		
2	↓	NG	NG	↓	N/A	N/A	N/A		
3		NG	NG		N/A	N/A	N/A		
4		+	+		Septated Hyphae		MEA MSCD > M		
5		NG	NG		N/A	N/A	N/A		
6		+	+		**	**	MEA MSCD > M		
7		NG	+		N/A	**	HEA : N/A MSCD : M		
8		NG	+		**	**	MEA MSCD > M		
9		+	+		↓	↓	MEA MSCD > M		
10		+	+				HEA MSCD > M		
11		+	NG		**	N/A	HEA : M MSCD : N/A		
12		NG	NG		N/A	N/A	N/A		
13		NG	NG		N/A	N/A	N/A		
14		+	NG		**	N/A	HEA: M MSCD : N/A		
15		NG	NG		N/A	N/A	N/A		
16		+	NG		**	N/A	MEA: M MSCD : N/A		
17		NG	+		N/A	**	MEA: N/A MSCD : M		
18		+	+		**	**	HEA MSCD > M		
19		+	+		↓	↓	HEA MSCD > M		
20		NG	NG		N/A	N/A	N/A		

ANALYST(S) Haydee B. Romero

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Key: Y = Pink Colony M = Blackish, gray Mold-like Colony NG = No Growth

GENERAL CONTINUATION SHEET	**PRODUCT** Methylpred AC (PF) 80MG/ML	**SAMPLE NO.** 693966

Results from Subculture of TH10 **Medium on agar plates**

N/A=Not Applicable

SUB #	**Agar used** 10/22/12 RR 11/1/12 RR			10/22/12 **Microscopic examination from**			**Colony Morphology**	**Subculture on**	**Biochemical identification** N/A
10/18/12 RR	MAC	MEA	MSCD	MAC	MEA	MSCD	10/22/12 RR	N/A	
21	NG	NG	+	N/A	N/A	* *	MEA : N/A MSCD : M		
22	↓	+	NG	↓	**	N/A	MEA : M MSCD: N/A		
23	↓	NG	NG	↓	N/A	N/A	N/A		
24	↓	+	+	↓	* *	* *	MEA MSCD > M		
25	↓	NG	NG	↓	N/A	N/A	N/A		
Blank Control	NG	NG	NG	N/A	N/A	N/A	N/A		

Exposure plates: No growth

* * Colony morphology same as sub # 4

QA #

MAC 284-12

MEA 283-12

MSCD 281-12

Chlorotetracycline 242-12

Blood agar plates BBL Lot 2220296 Exp. 2012.11.30 R'd 9/25/12

ANALYST(S) Haydee B Romero

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Key: Y = Pink colony M = Blackish, gray Mold-like colony NG = no growth

GENERAL CONTINUATION SHEET	PRODUCT Methylpred. AC (PF) 80MG/ML Injectable	SAMPLE NO. 693966

Results from Subculture of SCD Medium on agar plates

N/A=Not Applicable

SUB #	Agar used 10/22/12 & 11/1/12			10/22/12 Microscopic examination from			Colony Morphology	Subculture on	Biochemical identification N/A
10/18/12	MAc	MEA	MSCD	MAc	MEA	MSCD	10/22/12	N/A	
1	NG	+	+	N/A	yeast-like cells	yeast-like cells	MEA MSCD > Y		
2		+	+		* *	* *	MEA MSCD > Y		
3		+	+				MEA MSCD > Y		
4		+	+				MEA MSCD > Y		
5		+	+				MEA MSCD > Y		
6		+	+				MEA MSCD > Y		
7		+	+			* * * Septated Hyphae	MEA: Y MSCD: Y & M		
8		+	+			* *	MEA MSCD > Y		
9		+	+				MEA MSCD > Y		
10		+	+				MEA MSCD > Y		
11		+	+			* Septated Hyphae	MEA MSCD > Y & M		
12		+	+			* *	MEA MSCD > Y		
13		+	+			* *	MEA MSCD > Y		
14		+	+		* * * Septated Hyphae	* *	MEA MSCD > Y & M		
15		+	+				MEA MSCD > Y & M		
16		+	+		* *	* *	MEA MSCD > Y		
17		+	+				MEA MSCD > Y		
18		+	+				MEA MSCD > Y		
19		+	+				MEA MSCD > Y		
20		+	+		* * * Septated Hyphae	* *	MEA: Y & M MSCD: Y		

ANALYST(S) Haydee B Romero	PAGE 12 OF 13 PAGES

Key: Y = Pink colony M = Blackish, gray mold-like colony NG = No growth

NRL.MSB.NECC

Electronic Version of 431A

GENERAL CONTINUATION SHEET	PRODUCT Methylpred. AC (PF) 80MG/ML Injectable	SAMPLE NO. 693966

Results from Subculture of SCD Medium
on agar plates

N/A=Not Applicable

SUB #	Agar used 10/22/12 HR 11/1/12 HR			10/22/12 HR Microscopic examination from			Colony Morphology	Subculture on	Biochemical identification
10/18/12 HR	MAC	HEA	mSCD	MAC	HEA	mSCD	10/22/12 HR	N/A	N/A
21	↓	+	+	N/A	** Septated Hyphae	**	HEA : Y, M mSCD : Y		
22	↓	+	+	↓	** + Septated Hyphae	**	HEA mSCD > Y, M		
23	↓	+	+	↓	**	**	HEA mSCD > Y		
24	↓	+	+	↓	**	**	HEA mSCD > Y		
25	↓	+	+	↓	** + Septated Hyphae	**	HEA mSCD > Y, M		
Blank Control	NG	NG	NG	N/A	N/A	N/A	N/A		

Exposure plates: No growth

** Colony morphology same as Sub # 1

QA #

MAC 284-12

MEA 283-12

mSCD 281-12

Chlorotetracycline 242-12

Blood agar plates BBL Lot 2220296 EXP 2012.11.30 R'd 9/25/12

ANALYST(S) Haydee B Romero	PAGE 13 OF 13 PAGES

Key: Y = Pink colony M = blackish, gray mold-like colony NG = No growth

NRL MSB NECC

Electronic Version of 431A

SAMPLE NO.
693966
Sub #3
10/9/12

ATTACHMENT A

From Direct inoculation of Product onto MEA plate

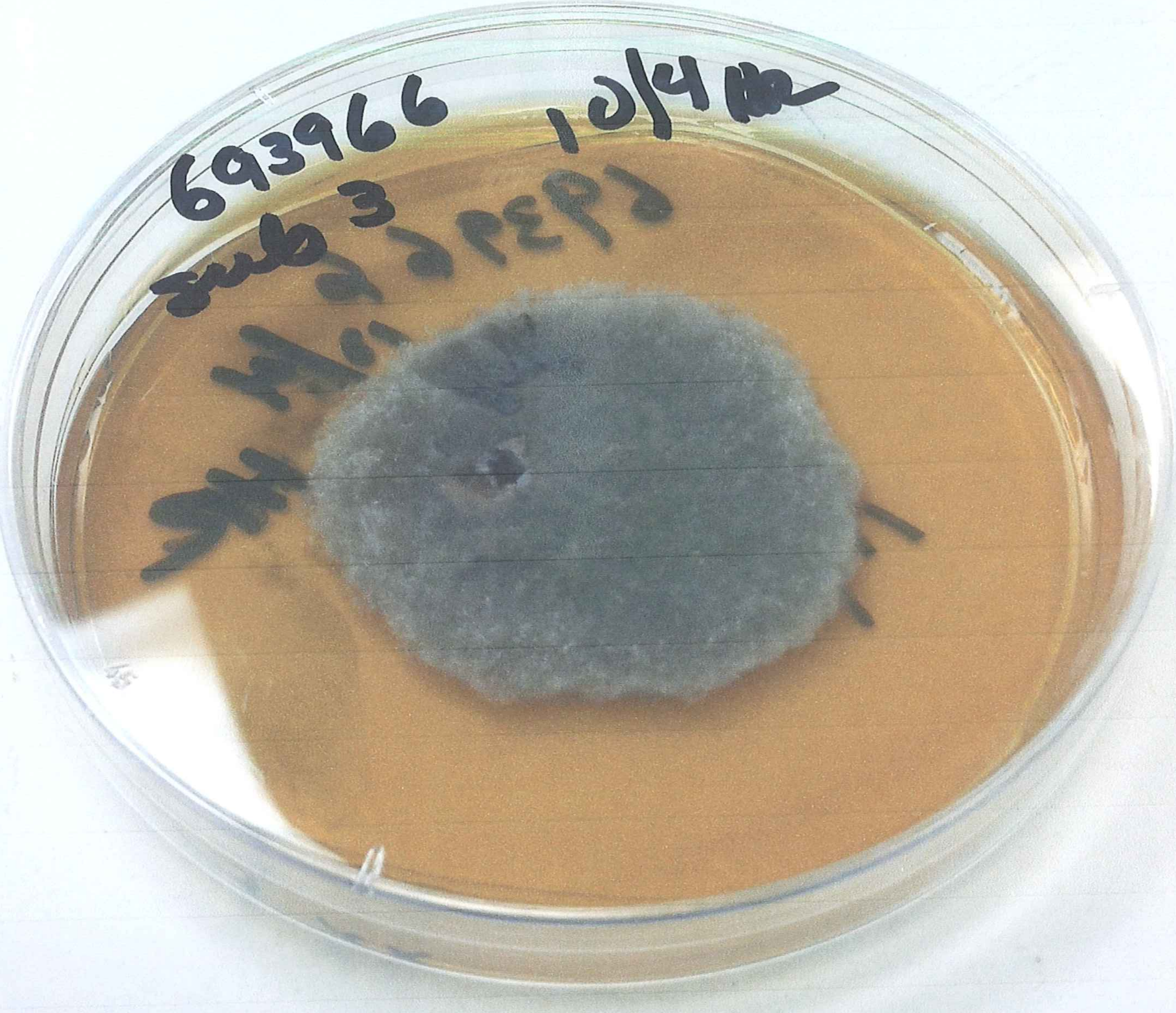


PHOTO TAKEN BY Josna Brant-Taornina 10/9/12

Photo taken by Josna Brant-Taornina 10/9/12

SAMPLE NO.
693966
10/9/12
Sub#3

ATTACHMENT B

Photocopy of microscopic examination of grey colony

Magnification 100X

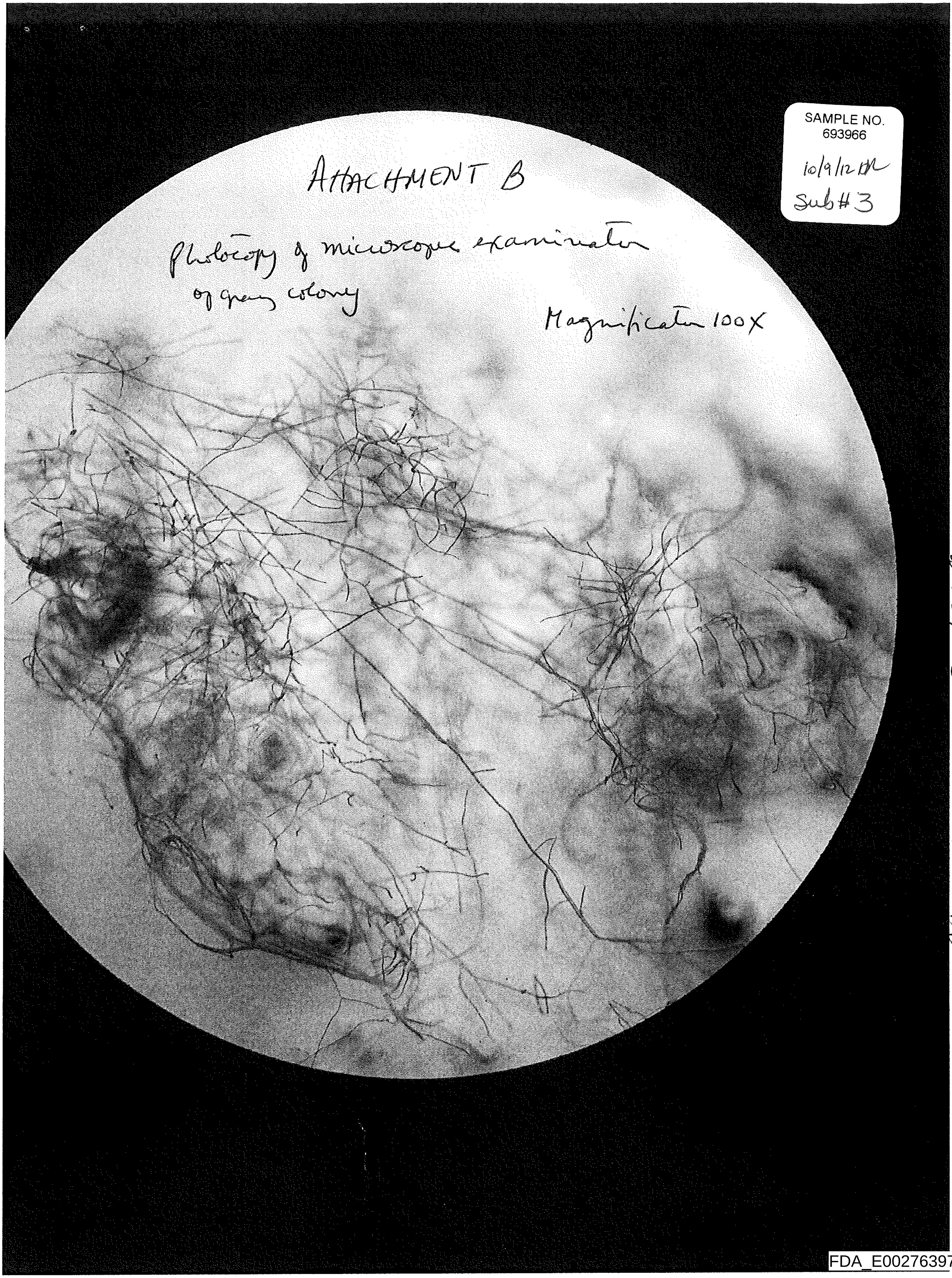
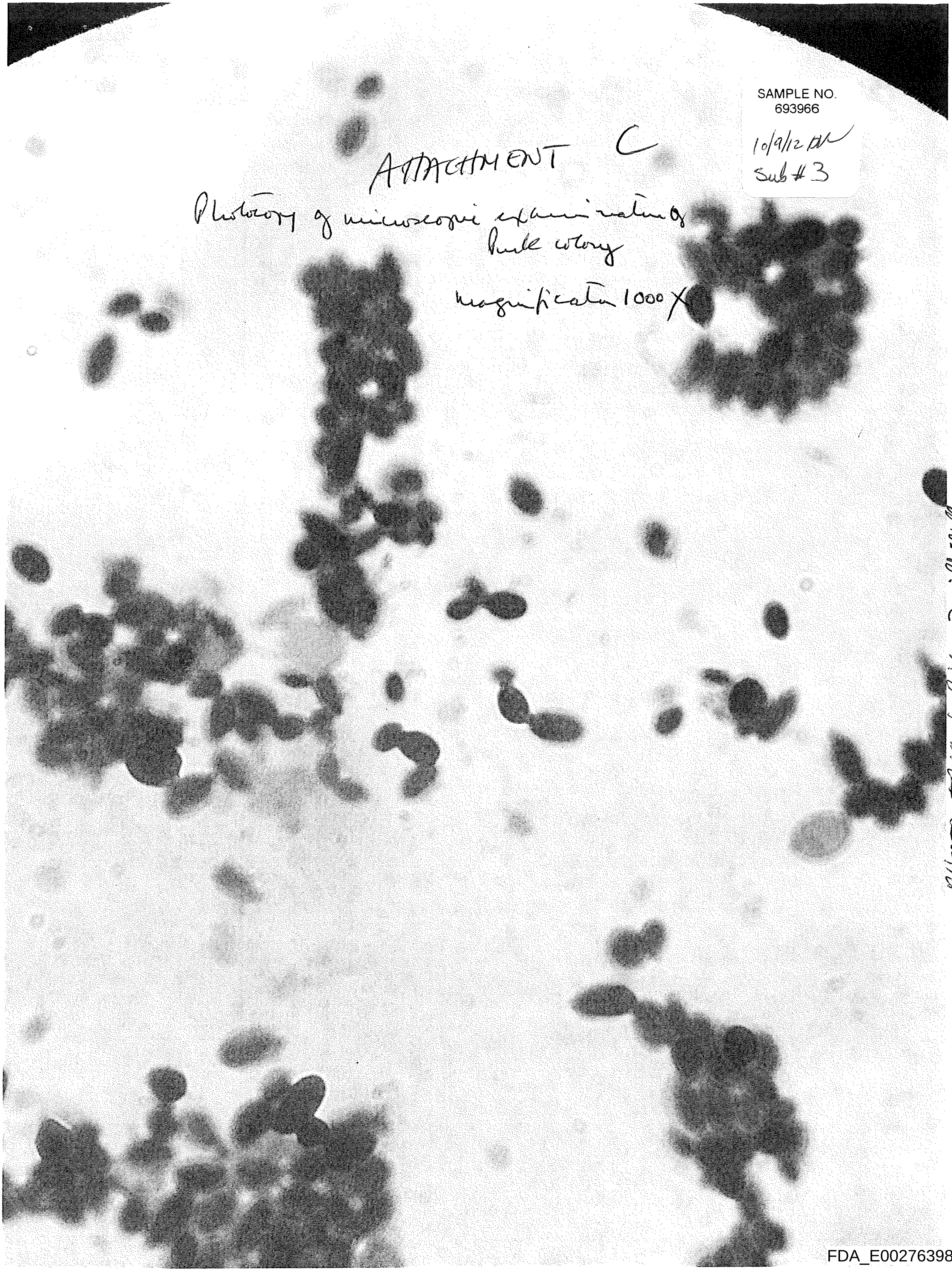


PHOTO TAKEN BY Daniel J O'Reilly



SAMPLE NO.
693966

10/9/12
Sub #3

ATTACHMENT C

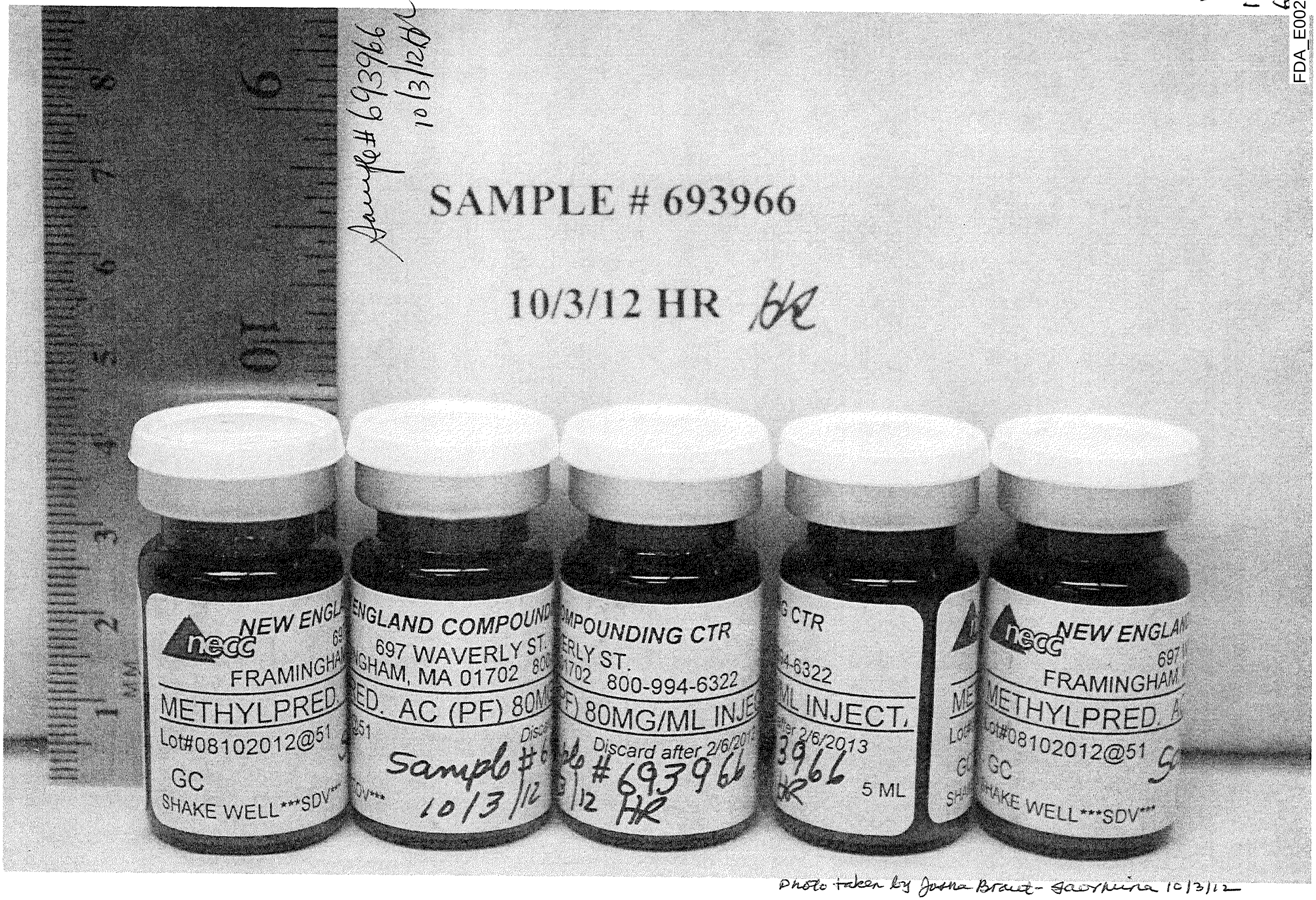
Photocopy of microscopic examination of Pink colony

magnification 1000X

PHOTO TAKEN BY Daniel J O'Reilly

12/10/12 HR

1 of 1


SAMPLE # 693966
10/3/12 HR HR
necc NEW ENGLAND COMPOUNDING CTR
697 WAVERLY ST.
FRAMINGHAM, MA 01702 800-994-6322
METHYLPRED. AC (PF) 80MG/ML INJECT.
Lot#08102012@51
Discard after 2/6/2013
GC
5 ML
SHAKE WELL***SDV***
Sample #693966 10/3/12 HR

Sample #693966 10/3/12 HR

Photo taken by Josha Brault-Gaorhuina 10/3/12

12/10/12 HR

1 of 1

~~676~~

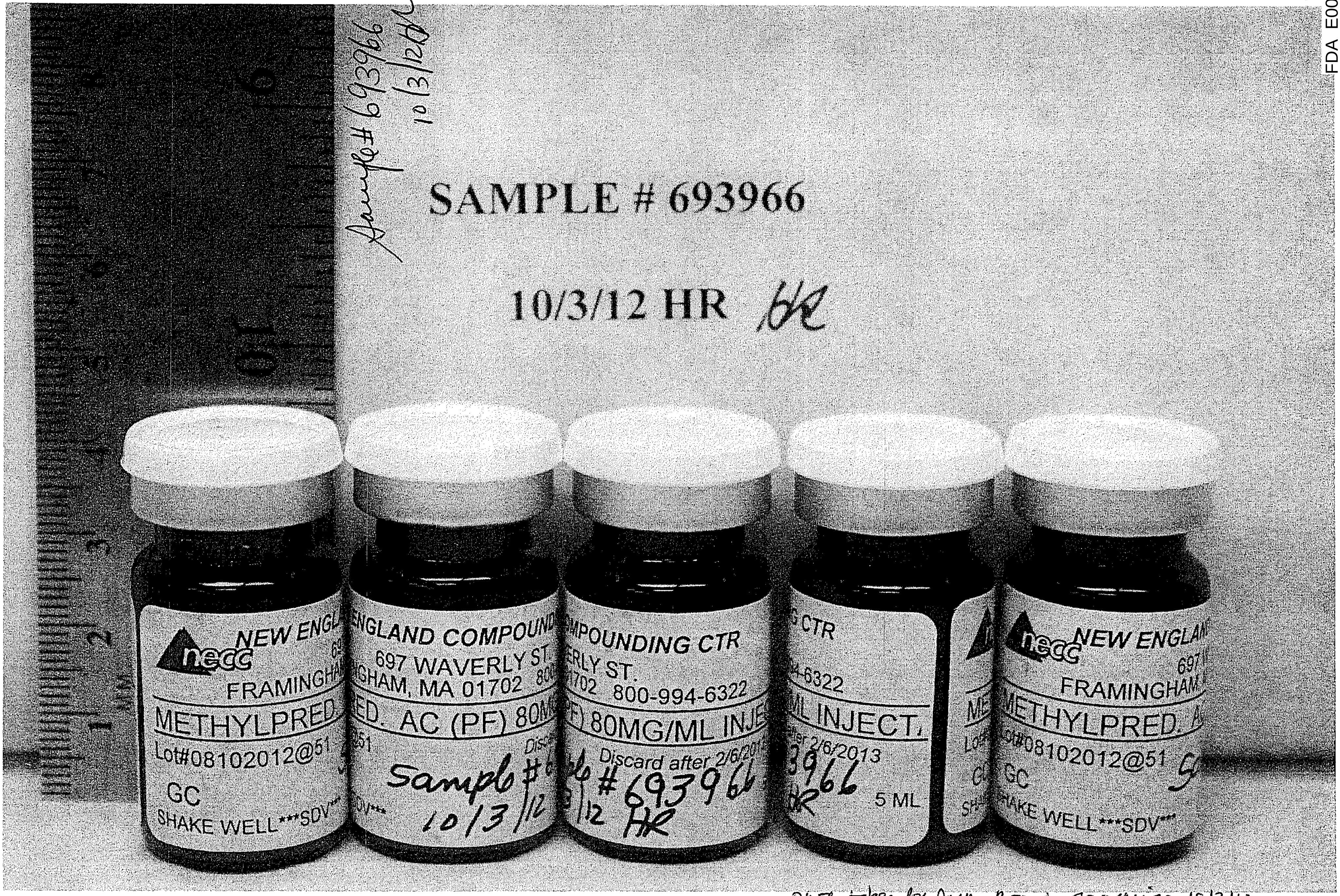


Photo taken by Joshua Braut-Gavrhina 10/3/12

12/10/12 HR

1 of 1
~~6 of 6~~

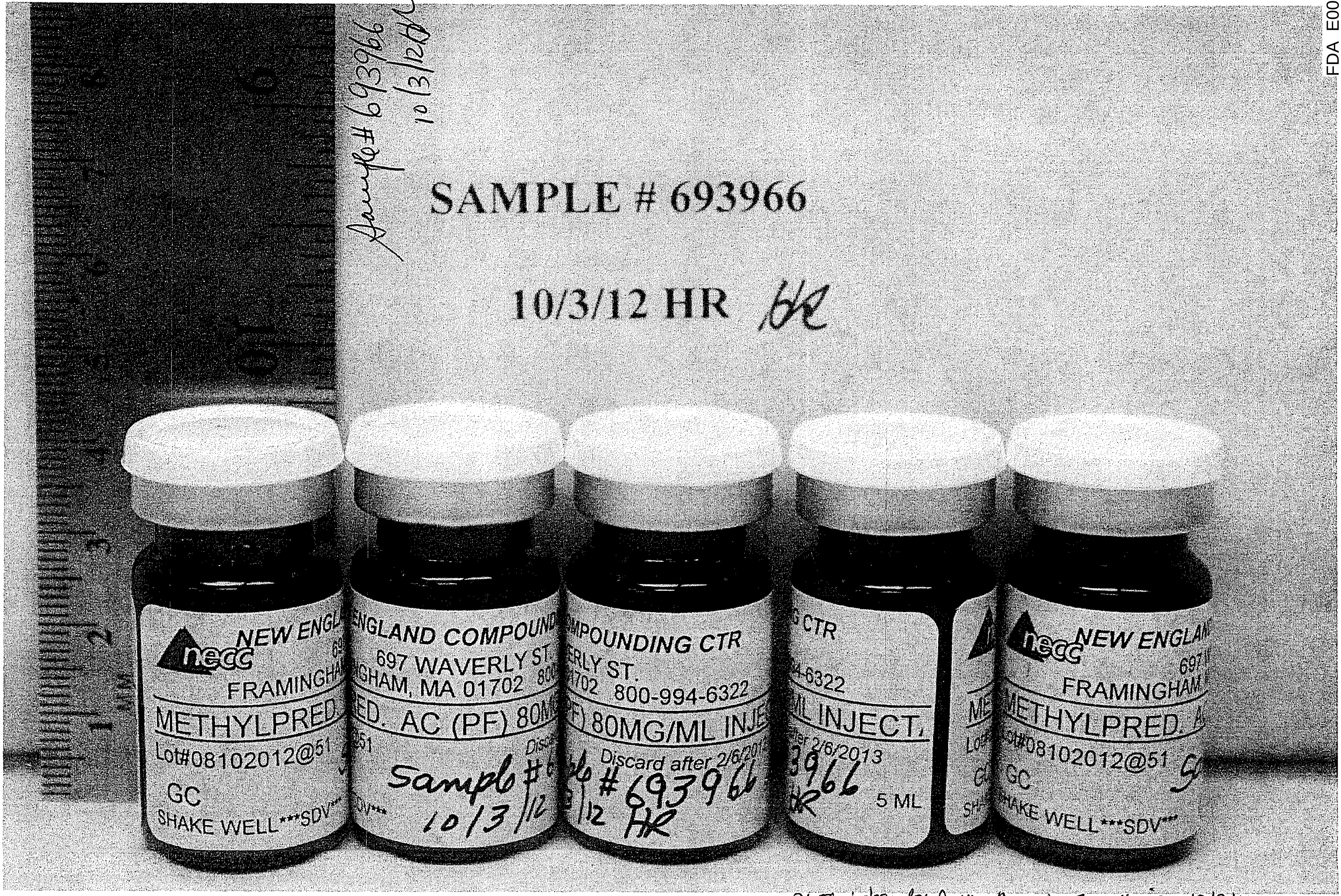


Photo taken by Joshua Brant-Sawyhina 10/3/12

Food and Drug Administration Office of Regulatory Affairs
Collection Report
For Sample Number: 693966 13206137

This is an accurate reproduction of the original electronic record as of 11/23/2012

Flag	**Flag Remarks**

Episode Number	**Origin**	**Basis**	**Sample Type**	**FIS Smpl Num**	**Status**
	Domestic	Other-Survln	Official	13206137	Completed
FEI	**Date Collected**	**Product Code**	**Responsible Firm**	**PAC**	**Hours**
3003623877	10/02/2012	64LCP45	Dealer	56D015	1.5
Compliance Num	**Country of Origin**				
70723	United States				
Related Smpl Num	**Position Class**	**Sampling District**	**NDC Number**	**Permit Number**	**Storage Rqrmnt.**
693965	INV	NWE-DO			Ambient
Dealer is Consumer	**Crx/DEA Schedule**	**Recall Num**	**Consumer Compl. Num**	**Brand Name**	
No				methylprednisolone acetate (preservative free) 80mg/ml	

Product Description
Product is a liquid sterile compounded suspension filled in 5mL amber glass vials and labeled as

Product Label
See continuation.

Reason for Collection	**MFG Codes**	**Expiration Date**
Sample collected to assess the presence of unknown particulate matter in sterile drug product, lot #08102012@51, intended for intrathecal administration. Sample collected during an inspection and will be tested for sterility and undergo visual inspection.	"08102012@51"	2/6/2013

Firm Legal Name	**Address**	**Type of Firm**	**Firm FEI**	**FCE**
New England Compounding Center	697 Waverly St Framingham, MA 01702-8589 US	Dealer	3003623877	
New England Compounding Center	697 Waverly St Framingham, MA 01702-8589 US	Manufacturer	3003623877	

Size of Lot	**Est. Value**	**Rcpt Type**	**Carrier Name**	**Date Shipped**
#231 five mL vials held in quarantine by firm		FDA484		

Description of Sample
Sample consists of #50 five mL vials of methylprednisolone acetate 80mg/mL suspension; lot #08102012@51

Method of Collection
See continuation.

How Prepared
See continuation.

Collector's Identification on Package and/or Label	**Collector's Identification on Seal**
"Sample #693966, SSD, 10/2/2012"	Please see remarks.

Sample Delivered To	**Date Delivered**	**Orig C/R & Records To**
NRL	10/03/2012	NWE-DO
	Lab w/Split Sample	**Lab**
	0	NRL

Document Number	**Document Date**	**Document Type**	**Document Remarks**
FDA 484	10/02/2012	Other	Copy of Receipt for Samples issued to Gregory A.

Conigliaro

Remarks
See continuation.

Payment Amount	**Payment Method**	**704(d) Sample**	**702(b) Portion**	**Collector's Name**
$0.00	No Charge	No	Yes	Stacey S Degarmo

Name of Signer	**Date & Time of Signature**			**Meaning**
Stacey S Degarmo	10/05/2012	07:33 PM	ET	Collector
Stacey S Degarmo	10/03/2012	03:52 PM	ET	Collector

Continuation:

Product Label

Drug product vials labeled in part: "necc NEW ENGLAND COMPOUNDING CTR 697 WAVERLY ST. FRAMINGHAM, MA 01702 800-994-6322 METHYLPRED. AC (PF) 80MG/ML INJECTABLE Lot #08102012@51 Discard after 2/6/2013 GC SHAKE WELL ***SDV*** 5ML "

Method of Collection

The sample of #50 five mL amber glass vials containing methylprednisolone acetate 80mg/ml suspension were collected from a bin containing #229 five mL vials. The vials were selected for sampling at random from the methylprednisolone drug product quarantined by the firm. Vials were placed in a brown paper bag.

How Prepared

At firm, Sample #693966 (#50 five mL amber glass vials of methylprednisolone acetate 80mg/ml suspension) were placed in a brown paper bag which was taped with filamentous tape as a closed package vertically, then horizontally across the opening. An official seal was affixed across the taped opening. The official seal read in part: "***New England District Office***693966***Stacey S. Degarmo,

Remarks

(continued from "Product Description") methylprednisolone AC (PF) 80mg/ml

(continued from "How Prepared") Investigator***10/2/2012***". The sample was placed in a locked briefcase for transport to the FDA office in Stoneham, MA. The sample was placed in locked drawer in NWE-DO overnight until 10/3/2012. On 10/3/2012, the sample was packaged with samples 693965 and 693967 (each affixed with a 525) in a corregated cardboard box lined with bubble wrap. The samples were hand delivered on 10/3/2012 to a representative from NRL by Investigator Mary McGarry.

Collector's ID on Seal: "New England District Office, 693966, Stacey S. Degarmo, Investigator, 10/2/2012"

Note: The sterile drug products sampled are compounded for intrathecal administration.

Note: The firm did not provide an estimated value of product lot #08102012@51.